



PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:

Fallaux et al.

Serial No.: 10/618,526

Filed: July 11, 2003

For: PACKAGING SYSTEMS FOR
HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY

Confirmation No.: 5055

Examiner: S. Priebe, Ph.D.

Group Art Unit: 1633

Attorney Docket No.: 2578-3833.9US

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REPLY BRIEF

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Attention: Board of Patent Appeals and Interferences

Sirs:

This Reply Brief is submitted under 37 CFR §§ 41.41(a)(1) and 41.43(b) within two months of August 28, 2007, the mailing date of the Examiner's Answer. The Answer raises new issues that require a response.

STATUS OF CLAIMS

Claims 1, 3-7, 10, 11, 16, and 21-25 are currently pending in the above-referenced patent application. Claims 1, 3-7, 10, 11, 16, 21-22, and 25 stand rejected under the judicially created doctrine of obviousness-type double patenting ("ODP"). Claims 23 and 24 have been allowed. Claims 2, 8, 9, 12-15, and 17-20 have been cancelled. The ODP rejections of claims 1, 3-7, 10, 11, 16, 21, 22, and 25 are being appealed.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3-7, 10, 11, 16, 22, and 25 stand rejected over the judicially created doctrine of obviousness-type double patenting (ODP) over claims 43 and 44 of U.S. Patent 6,340,595 and claims 7, 32, and 35 of U.S. Patent 6,413,776.

U.S. Patents 6,340,595 and 6,413,776 are referred to collectively in appellant's brief.

ARGUMENT

37 CFR 1.321 Terminal Disclaimers

The first full paragraph on page 4 of the Answer is not directly responsive to Appellant's argument. Appellant does not contend that a terminal disclaimer cannot be filed under the facts of this case. Rather, Appellant contends that the terminal disclaimer filed and entered in this case is sufficient to overcome the ODP rejection. The possibility of a term extension has been eliminated. Appellant is disqualified (because of the facts of ownership) from complying with the specific requirements of 37 CFR 1.321(c), but has complied with 37 CFR 1.321(b). Appellant contends that it has done all that should be required to overcome the ODP rejection under the facts of this case.

The Two-Way Test

Starting at the second full paragraph on page 4, the Answer is primarily based upon *In re Emert*, 124 F.3d 1458 (Fed. Cir. 1997). The *Emert* decision distorts both the facts and the reasoning of *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991). Significantly, the *Braat* court did not purport to establish or adhere to a two-condition test; it merely noted the reality that applicants do not ordinarily have complete control over the rate of progress of applications through the USPTO. It then linked this reality to the policy enunciated by its predecessor court in *In re Borah*, 354 F.2d 1009 (C.C.P.A. 1966) and the analysis set forth in DONALD S. CHISUM, CHISUM ON PATENTS §9.03[2][c] (1990); namely, the relevant inquiry is whether an improvement is patentably distinct from the generic invention, without regard to their order of issuance. While *Borah* dealt with circumstances in which a later filed improvement patent issued before an earlier filed basic patent, the *Braat* court extended the *Borah* policy to appellant's circumstances. "[A]pplications for basic and improved patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicant does not have complete control." *Braat*, 937 F.2d at 1292.

The Answer asserts that *Emert* "explains" that two conditions must be met to qualify for the two-way test applied by the court in *Borah*. More accurately, *Emert* acknowledges that the Federal Circuit has set forth two tests for obviousness-type double patenting rejections; the two-way test of *Braat*, and the one-way test of *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993). *Emert*,

124 F.3d at 1461. Neither test is characterized by *Emert* as requiring that two conditions be met. That is a formalism found only in the Answer.

According to *Emert*, *Braat* applied a two-way test because “the applicant filed two applications, the second of which issued first due to the PTO’s unjustified delays in the prosecution of the first application.” *Id.* That reading of *Braat* is inaccurate. The Answer acknowledges that “. . . as in the instant case, the Braat application was filed after the reference patent (Dil), but based upon applications filed prior to the reference patent, and . . . the Dil patent was a non-obvious improvement over the invention of Braat.” *Examiner’s Answer, mailed August 28, 2007*, pg. 4, lns. 14-16. Significantly, the referenced Dil patent issued some three and a half years prior to filing of the Braat application. In fact, the *Braat* court made no mention of any administrative delay attributable to the PTO. To the extent that the *Emert* court suggests otherwise, it is mistaken, and cannot fairly be relied upon to support the rejection in this case. Improper delay by either Appellant or the PTO could not possibly have been a factor in the *Braat* decision; neither should it be in this case.

The Answer acknowledges that the claims under rejection could not have been presented in the reference patent. *See Examiner’s Answer, mailed August 28, 2007*, pg. 5, ln. 2. The argument beginning at page 5, line 3 of the Answer is inconsistent with that admission. In any case, the instant record lacks any evidence that either the PTO or Appellant has caused any delay in prosecution, a pivotal established fact in *Emert*.

Emert differs procedurally and factually from *Braat*. The *Emert* court was called upon to review factual findings made by the PTO underlying its decision to use a one-way analysis. *Emert*, 124 F.3d at 1460. These findings were reviewed for clear error. *Id.* Because no such error was noted, the PTO determination was affirmed as proper. In other words, it was taken as established that *Emert* was responsible for significant willful delays in prosecution, viz. “*Emert* had significant control over the rate of prosecution of the application.” *Id.* at 1461. “The ultimate determination of whether a one-way or two-way analysis is appropriate is also a question for the court.” *Id.* at 1460. “Because *Emert* orchestrated the rate of prosecution of the two applications, this court applies a one-way analysis.” *Id.* at 1461.

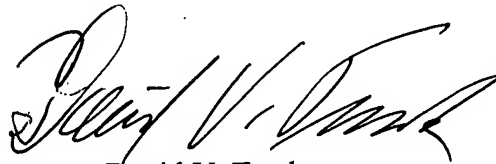
It seems clear that both *Braat* and *Emert* considered the ODP rejections before the respective panels of the court on a case-by-case basis. The facts of the instant case are close, in

all material respects, to those considered by the *Braat* court. They are dissimilar from the facts regarded as compelling by the *Emert* court. Accordingly, a two-way analysis is appropriate in this case, consistent with the reasoning of both of those decisions.

CONCLUSION

The ODP rejections of claims 1, 3-7, 10, 11, 16, 21-22, and 25 should be reversed, and each of these claims should be allowed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David V. Trask", with a stylized, cursive script.

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